

**REMARKS**

Claims 2-20, 24, 26-28, 31, 46, 48-53 and 55 are pending. Claims 14-18, and 55 have been withdrawn as directed to non-elected subject matter there being no allowable generic or linking claim at this time. Claims 2, 13, and 24 have been amended to correct typographical or other non-substantive matters. Claim 2 has also been amended to specify the type of administration. Claim 56 has been added to specify the route of administration is intravenous. Claims 57 and 58 have also been added. Support for the amendments can be found throughout the specification. Upon entry of this amendment claims 2-13, 19, 20, 24, 26-28, 31, 46, 48-53, and 56-58 are subject to examination. These amendments find support in the specification and the previously submitted claims; thus, no new matter is presented. Each of the objections and rejections set forth in the Office Action are addressed below in the order presented therein

***Priority***

Applicants acknowledge Examiner's request for a certified translation of the priority document. Applicants submit herewith a certified translation of the priority document.

***Objections***

Claims 2 stands objected to for allegedly incorrect antecedent basis. Applicants have amended claim 2, which obviates the rejection.

Claim 13 stands objected to for allegedly failing to further limit the claim from which it depends. Claim 13 has been amended, which obviates the rejection.

Claim 24 stands objected to for depending upon a cancelled claim. Applicants thank the Examiner for assuming that the claim should depend from claim 2. Applicants have amended claim 24 to depend from claim 2, thereby obviating the objection.

In view of the foregoing, Applicants respectfully request that the objections to the claims be withdrawn.

*Rejections under 35 U.S.C. § 102*

Claims 2, 5, 7-13, 24, 26-28, 31, and 50 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Carter (U.S. Patent No. 5,712,257), as evidenced by Rummelt et al (Ophthalmology 101(2):270-279, 1994; Abstract only). Applicants respectfully disagree.

Applicants note that the Office's interpretation of the term "naked" and "comprising" is incorrect. Although the Office is correct in noting that the term "comprising" is open-ended, the interpretation of the claim must still be reasonable in view of the specification and the plain language of the claim. The Office alleges that the present specification states that dsRNA can be delivered with other carriers and, therefore, "naked" can be construed to include "encapsulating naked dsRNA molecules." (Office Action, page 6). The Office's interpretation is incorrect and repugnant to the plain meaning and the meaning put forward in the specification. One of skill in the art would understand that the meaning of the term "naked" means that it is not encapsulated by a micelle or liposome. If a dsRNA is encapsulated, by definition it is not naked. Using the Office's interpretation, if a claim recited "a composition comprising a naked person" that person could be reasonably interpreted to be encapsulated by clothing. If such an interpretation were used the person would no longer be naked because it would be repugnant to the definition of naked. Accordingly, the Office's interpretation is not reasonable because it contradicts what is actually claimed.

Notwithstanding, the Office's unreasonable interpretation, the Carter reference fails to anticipate the claims. The Carter reference discusses administering mismatched dsRNA molecules. The pending claims recite that the dsRNA molecules are not mismatched, but rather are complementary. Additionally, the Carter reference fails to teach or suggest parental administration. The Carter reference states that the compositions disclosed can be applied topically. Accordingly, the Carter reference fails to teach each and every element of the claim, and, therefore, fails to anticipate the presently claimed invention.

Claims 2-13, 19-20, 24, 26-28, 31, 46, 48, 50 and 54 stand rejected under 35 USC § 102(a) and 35 U.S.C. § 102(e) as allegedly being anticipated by King (U.S. 2002/0165158 A1),

as evidenced by Caplen (Trends in Biotech. 20(2):49-51, 2002). Applicants respectfully disagree.

Applicants refer the Office to Applicants statements above regarding the Office's unreasonable interpretation of the terms "comprising" and "naked." The King reference fails to anticipate the presently claimed invention. The King reference does not teach naked dsRNA. As discussed above, the Office's interpretation of the claim is not reasonable because it would be repugnant to one of skill in the art reading the claim. For this reason and the reasons stated above, the King reference cannot anticipate the pending claims because the King reference fails to teach or suggest a naked dsRNA as presently claimed.

Claims 2, 5-10, 13, 19-20, 24, 26-28, 31, and 48-53 stand rejected under 35 USC § 102(e), in light of Tolentino et al. (U.S. Patent No. 7,148,342). Applicants enclose herewith a certified translation of the present application's priority document. Accordingly, the Tolentino reference is not prior art. As acknowledged by the Examiner, the priority date of the present application is April 18, 2002. The Tolentino reference claims priority to a provisional application that was filed July 24, 2002. Accordingly, the Tolentino reference is not prior art against the present application.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. §102 be withdrawn.

#### ***Rejection under 35 U.S.C. § 103***

Claims 2-13, 19-20, 24, 26-28, 31, 46, and 48-53 are rejected under 35 U.S.C. §103(a), in light of Robinson et al. (U.S. Patent No. 5,814,620) in view of LeFleur et al. (U.S. Patent No. 6,433,145), and Tuschl et al. (U.S. Patent Application No. 2002/0086356). Applicants respectfully disagree.

The claims are not obvious because the combination of the references fails to yield the presently claimed invention. The combination of the references does not yield a composition comprising naked dsRNA. As discussed above, the Office's interpretation of the term "comprising" as it relates to the term "naked" is not reasonable. The Office's interpretation is

repugnant to the present specification and the plain meaning of the terms. One of skill in the art would not consider encapsulated dsRNA to be naked dsRNA. By definition, encapsulated cannot mean naked. Accordingly, the claims are not obvious because the combination does not yield the presently claimed invention.

The claims are also not obvious, even if the combination yielded the presently claimed invention, because the Office has failed to show that one of skill in the art would have had a reasonable expectation of success performing the claimed method with naked dsRNA. As discussed previously, there is no indication that naked dsRNA can even cross the blood-brain or the blood-retina barrier. The additional references to other elements of the claims merely recite added elements, without addressing this primary deficiency. As such, the references do not teach or even suggest each and every element of the claims with a reasonable expectation of success. The Office's response to this fact is to use an unreasonable interpretation of the claims to show that the combination yields the presently claimed invention. Applicants respectfully assert that in view of a reasonable interpretation of the claims, the obviousness rejection must be withdrawn.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

**CONCLUSION**

For the reasons discussed above, Applicant respectfully requests reconsideration of the rejections of the claims. Applicant believes that these claims are in proper form for allowance. If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below.

It is not believed that any additional fees are due; however, in the event that an additional fee is required for this response, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-0436.

Respectfully submitted,



By: \_\_\_\_\_

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Attachments: Certified Translation of Priority Document